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Tennessee Valley Authority			Leung, Jennifer A	
Darlene Stevenson CTR 1C P O Box 1010		ART UNIT	PAPER NUMBER	
Muscle Shoals, AL 35662-1010			1764	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>			/			
		Application No.	Applicant(s)			
		09/518,642	HOLT, GRADY LYNN			
Office Action Summary		Examiner	Art Unit			
		Jennifer A. Leung	1764			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)	Responsive to communication(s) filed on 22 S	eptember 2003.				
2a)⊠	This action is FINAL . 2b) ☐ This	action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	ion of Claims					
5)□ 6)⊠ 7)□	 ☐ Claim(s) 1-18 is/are pending in the application. 4a) Of the above claim(s) 8-10,13,14 and 16 is/are withdrawn from consideration. ☐ Claim(s) is/are allowed. ☐ Claim(s) 1-7,11,12,15,17 and 18 is/are rejected. ☐ Claim(s) is/are objected to. ☐ Claim(s) 1-18 are subject to restriction and/or election requirement. 					
Application Papers						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. §§ 119 and 120						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.						
Attachmen						
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) D Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)			

Art Unit: 1764

DETAILED ACTION

Response to Amendment

1. Applicant's amendment submitted on September 22, 2003 has been received and carefully considered. Claims 1-18 remain active. Claims 8-10, 13, 14 and 16 are withdrawn from consideration. Claims 1-7, 11, 12, 15, 17 and 18 stand rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 4, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917).

Regarding claims 1 and 17, Ogle (FIG. 1-9; column 3, lines 1-65) discloses a compressible reactor/system comprising:

- a single-use vessel (i.e. outer container 10) holding a volume of treatment chemical and a frangible container (i.e. inner container 48 having a pierceable cap 52, hence "frangible") which may contain a toxic chemical, depending on the intended use (column 1, lines 9-12; column 2, lines 14-16); said single-use vessel 10 having a compressible section (i.e. accordianlike undulations 32) and a lower treatment portion (i.e. the chamber, as defined by the walls of outer container 10) having a means for fixing the frangible container 48 to the lower treatment portion (i.e., bottom most undulation 32 snap fitted to indentations 50; column 3, lines 27-31; see also FIG. 15 and 16 for another configuration);
- a cover (i.e. end closure 14) fastened to said single use vessel 10; and

Art Unit: 1764

an impact member (i.e. projection 34) fixed to said cover 14, wherein upon compression of said compressible section 32, said impact member 34 approaches and breaks said frangible container 48, 52 (FIG. 3).

Ogle discloses that for the means for compressing the compressible section, "the user simply compresses the package in an accordianlike fashion as shown in FIG. 3 to cause the projection 34... to pierce the cap 52 on the inner container 48," (column 3, lines 37-41). However, Ogle is silent as to whether the user's means for compressing may comprise a jack and compression support frame, such that the jack is operative to extend between the cover and compression support frame to compress the compressible section. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to substitute a jack and compression support frame for the means for compressing in the apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the provision of mechanical or automated means to replace manual activity was held to have been obvious, In re Venner 120 USPQ 192 (CCPA 1958); In re Rundell 9 USPQ 220 (CCPA 1931), and the substitution of one known equivalent technique for another may be obvious even if the prior art does not expressly suggest the substitution, Ex parte Novak 16 USPQ 2d 2041 (BPAI 1989); In re Mostovych 144 USPQ 38 (CCPA 1964); In re Leshin 125 USPQ 416 (CCPA 1960); Graver Tank and Manufacturing Co. v. Linde Air Products Co. 85 USPQ 328 (USSC 1950). Furthermore, the use of jacks, coupled with a support frame, as a means for compressing is conventionally known in the art, as evidenced by Chaignay. In particular, Chaignay (Abstract, Figures) teaches a small hydraulic press comprising a jack (FIG. 2) attached to the upper surface 5 of a surrounding frame (comprising components 1, 2, 5),

Art Unit: 1764

wherein in operation, an object (i.e. the compressible reactor of Ogle) which is placed upon the base of the frame is compressed by the jack via extension of the extendable shaft 20 (FIG. 1).

In view of the newly added limitations, the collective teachings of Ogle and Chaignay are silent as to compressible section 32 being located in the upper portion of the apparatus. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select such a location for the compressible section 32 in the modified reactor/system of Ogle, because whether the compressible section is located in the upper portion of the container or the lower portion of the container serves the substantially identical function of providing a means for actuating the impact member 34 so as to approach and pierce frangible container 48. Such concept is evidenced by J. De Santo et al., who teach an apparatus adapted to contain two different types of fluid in separate compartments, whereby the fluids can be mixed together when desired for use. In particular, the apparatus comprises a single use vessel 10 having pleats 14 located in an upper portion of the vessel (see FIG. 2). Upon expansion of pleats 14 (see FIG. 5) a central valve stem 38 is actuated upwards. Upon compression of pleats 14, the central valve stem 38 would, inherently, be actuated downwards. Thus, lower compressible section 32 of Ogle and upper pleats 14 of J. De Santo comprise substantial equivalents structurally and functionally, and it has been held that the substitution of known equivalent structures involves only ordinary skill in the art. In re Fout 213 USPQ 532 (CCPA 1982); In re Susi 169 USPQ 423 (CCPA 1971); In re Siebentritt 152 USPQ 618 (CCPA 1967); In re Ruff 118 USPQ 343 (CCPA 1958).

Regarding claim 3, Ogle discloses frangible container 48, 52 may be made of glass (column 3, lines 21-22), hence comprising a "glass ampoule".

Art Unit: 1764

Regarding claim 4, although Ogle is silent as to whether frangible container 48, 52 may contain a chemical weapon material, Ogle further discloses container 48, 52 and vessel 10 are "generally applicable to the storage and mixing... of any two reactive or nonreactive liquids or to the mixing of any liquid and solid," (column 1, lines 9-12), and the device is, "particularly adapted for the handling of reactive, toxic and/or noxious chemicals," (column 2, lines 14-16). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select an appropriate chemical, such as a chemical weapon material, for the chemical in the modified apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof.

Regarding claim 7, Ogle discloses, "closure 14... has a lip 24 which engages and forms a seal on the upper end 26 of container 10," (column 3, lines 5-7). A gasket may be defined as, "any of a wide variety of seals or packings used between matched machine parts or around pipe joints to prevent the escape of a gas or fluid," (The American Heritage® Dictionary of the English Language, Fourth Edition. Copyright © 2000 by Houghton Mifflin Company).

Therefore, lip 24 of Ogle meets the claim of a "cover gasket".

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917), as applied to claim 1 above, and further in view of Loper (U.S. 3,087,638).

Ogle (FIG. 1-8; column 3, lines 2-4) discloses cover **14** may comprise a means for sampling the mixed chemicals, wherein the means comprises a dispensing spout **16** having a fluid passage **18**. However, Ogle is silent as to whether the means may comprise a septum formed within said cover. In any event, it would have been an obvious design choice for one of

Art Unit: 1764

ordinary skill in the art at the time the invention was made to select a septum for the means for sampling in the modified apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the use of a septum as a means for sampling is conventionally known in the art, as evidenced by Loper. In particular, Loper teaches a septum (piston plug 30) for allowing a user to sample the contents of a container 15 using a piercing needle, wherein the needle is inserted through the penetrable material on the topside 29, 29a, 29b of the piston plug (Figures; column 1, lines 9-28; column 2, lines 70-73; column 3, lines 43-51). Furthermore, substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

4. Claims 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917), as applied to claim 1 above, and further in view of Bolduc (U.S. 5,064,121).

Regarding claims 5 and 6, Ogle discloses the frangible container may comprise indentations 50, "adapted to receive the inner edge of the bottom most of the accordionlike undulations 32 with a snap fit," such that, "the container 48 is restrained from longitudinal movement with respect to the outside container 10," (column 3, lines 25-31), essentially functioning as a holding means for container. However, Ogle is silent as to whether the holding means may comprise a cradle for holding the container, wherein the cradle comprises penetrations. Bolduc (FIG. 1, 3, 6) teaches an apparatus for separately storing, mixing and dispensing two chemicals, similar to the apparatus of Ogle, wherein the apparatus comprises a single-use vessel (external bottle or container 11) holding a frangible container (ampule or vial)

Art Unit: 1764

49), wherein the mixing of the chemicals is initiated by the breaking container 49 with an impact member (push rod 42). In particular, container 49 is held in place by a cradle (holder 53), which comprises a plurality of penetrations (vent holes 55). It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide a cradle comprising penetrations for the holding means in the modified apparatus of Ogle, because holder 53 provides a rigid support for frangible container 49 while facilitating mixing of materials via penetrations 55, as taught by Bolduc (column 3, lines 9-12, 48-50; column 7, lines 2-5, 58-61). Furthermore, substitution of known equivalent structures involves only ordinary skill in the art.

Regarding claim 18, Ogle (FIG. 1-8; column 3, lines 1-50) discloses a method of treating a toxic chemical (column 2, lines 14-17) using the apparatus as disclosed in claim 1 above, comprising the steps of:

- placing the frangible container (comprising inner container 48, cap 52) in said single-use
 vessel 10 so that said frangible container 48, 52 is internally aligned with an impact
 member (projection 34);
- inserting the treatment chemical (column 1, lines 9-12; column 4, lines 28-37) into said single use vessel 10; and
- sealing said single-use treatment vessel 10 by providing an end closure 14 having a lip 24
 that engages and forms a seal on the upper end 26 of container 10;

wherein the elements are, "assembled in the fashion as shown in FIG. 1." (column 3, lines 34-37). However, Ogle is silent as to the particular order for conducting the steps above for obtaining the structure shown in FIG. 1.

Bolduc (FIG. 1, 3, 6; column 8, lines 23-34) teaches an apparatus for mixing and

Art Unit: 1764

dispensing two chemicals that are separately stored, similar to the apparatus of Ogle, wherein the method for using the apparatus comprises the steps of:

- first, placing a frangible container (sealed ampule 49) into a single-use vessel 11 so that
 said frangible container 49 is internally aligned with an impact member (push rod 42);
- second, inserting a treatment chemical (i.e. material 17) into said single use vessel; and
- third, sealing said single-use treatment vessel 11 with cap 18.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to conduct the steps according to the order of Bolduc in the method of Ogle, since both processes are substantially identical or equivalent in terms of function, manner and result, and it has been held that the where the processes are substantially identical or equivalent in terms of function, manner and result, transposition of process steps or the splitting of one step into two does not patentably distinguish the processes. *Ex part Rubin* 128 USPQ 159 (PO Bd PatApp 1959).

Ogle further discloses that following assembly, "when it is desired to admix the two ingredients, the user simply compresses the package in an accordionlike fashion as shown in FIG. 3 to cause the projection 34 with its sharp cutting edges 38 to pierce the cap 52 on the inner container 48," (column 3, lines 37-41), which in the modified apparatus, would comprise the step of operating the jack so that a force is exerted on the compressible section (see comments made with respect to Chaignay in claim 1 above). However, Ogle is silent as to shaking the vessel to facilitate mixing between the treatment chemical and said toxic chemical. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention to shake the contents of the vessel in the modified method of Ogle, since it is well known in the art that agitation by means of shaking facilitates mixing. Such is evidenced by Bolduc, who teaches that

Page 9

Application/Control Number: 09/518,642

Art Unit: 1764

"mixing of materials can be facilitated by shaking dispenser 10." (column 7, lines 54-58).

- 5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519), J. De Santa et al. (US 3,221,917) and Bolduc (US 5,064,121). The same comments with respect to Ogle, Chaignay, J. De Santa and Bolduc apply (see claims 1 and 18 above).
- 6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519), J. De Santa et al. (US 3,221,917) and Bolduc (US 5,064,121), as applied to claim 11 above, and further in view of Loper (U.S. 3,087,638).

Ogle (FIG. 1-8; column 3, lines 2-4, 48-50) discloses the step of dispensing or "sampling" the mixed chemicals from the apparatus via a sampling means comprising a dispensing spout 16 and a fluid passage 18, but is silent as to the sampling means comprising a septum. The same comments with respect to Loper apply (see claim 2 above).

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519).

The same comments with respect to Ogle and Chaignay apply (see claim 1 above).

Response to Arguments

- 8. Applicant's arguments regarding the rejections of claims 1-7, 11, 12, 17 and 18 have been considered but are most in view of the new grounds of rejection, as necessitated by the amendments to claims to recite "an upper compressible section" and "a lower treatment portion".
- 9. Applicant's arguments with respect to the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) have been

Art Unit: 1764

fully considered but they are not persuasive, since it is noted that the claim still recites "a compressible section" and "a treatment portion", with no limitation of location to an upper or lower portion, respectively.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* * *

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is (571) 272-1449. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on (571) 272-1444. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung December 17, 2003

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Page 10